

**CLAIMS****What is claimed is:**

- 5           1.       An implantable cardiac lead having a distal tip, the distal tip including a drug dispensing means for dispensing a drug in the form of a monolithic controlled release device (MCRD) mixture at an implant site, the MCRD mixture comprising:
- an inflammation-reducing drug component; and
- 10                 a drug component carrying silicone elastomer.
2.       The lead of claim 1 wherein the silicone elastomer comprises a base component and a curing component.
- 15           3.       The lead of claim 2 wherein the curing component comprises a platinum catalyst.
4.       The lead of claim 2 wherein the base component comprises a mixture of a dimethyisloxane polymer and a reinforcing silicone .
- 20           5.       The lead of claim 1 wherein the drug component comprises a steroid.
6.       The lead of claim 5 wherein the steroid comprises
- 25           dexamethansone sodium phosphate.
7.       The lead of claim 5 wherein the drug component includes a silicone fluid for facilitating mixing of the drug component with the silicone elastomeric.
- 30           8.       The lead of claim 2 wherein the dispensing means is configured in the form of a plug adapted to be carried by the distal tip.

9. A method of manufacturing a drug-eluting lead containing drug-eluting means for dispensing a drug, the lead having a distal tip, the method comprising the steps of:

- 5                    providing said endocardial lead;  
                     combining an inflammation-reducing drug with a drug  
                     carrying silicone elastomer to form a mixture thereof;  
                     applying the mixture to the distal tip of the lead; and  
                     allowing the mixture to cure in place in the lead.

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10. The method of claim 9 wherein the step of combining comprises the steps of:

- combining a wetting fluid component and the inflammation-  
                     reducing drug to form a first mixture;  
15                    combining the first mixture and a base component to form a  
                     second mixture;  
                     combining the second mixture and a curing component to  
                     form a third mixture;  
                     applying the third mixture into the distal tip of the lead; and  
20                    curing the third mixture applied to the tip at a predetermined  
                     temperature.

11. The method of claim 10 wherein the curing step comprises the step of elevating the temperature to the predetermined value being in the range of about 40 degrees C to 75 degrees C.

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12. The method of claim 10 wherein the step of combining to form a first mixture comprises the step of providing a steroid for the inflammation-reducing drug.

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13. The method of claim 10 wherein the step of combining to form a second mixture comprises the step of providing a mixture of

dimethylsiloxane polymer and a reinforcing silicone for the base component.

14. The method of claim 10 wherein the step of combining to  
5 form a third mixture comprises the step of providing a platinum catalyst for the curing component.

15. The method of claim 11 wherein the curing step comprises  
10 setting the predetermined temperature to 55 degrees C.

16. An apparatus for forming a monolithic controlled release  
device (MCRD) mixture, for use in a drug-eluting endocardial lead having  
a distal tip, to facilitate the controlled release of the drug from the distal tip  
into cardiac tissue, the apparatus comprising:

15 a first container adapted to contain a base component;  
a second container adapted to contain a curing component;  
a third container adapted to contain a drug component;  
a fourth container adapted to contain a wetting fluid;  
a second mixer adapted to form a drug mixture of the drug  
20 component and the wetting fluid;  
a third mixer adapted to form a third mixture of the drug  
mixture and the base component; and  
a first mixer adapted to form a first mixture of the third  
mixture and the curing component.

25 17. The apparatus of claim 16 comprising a dispenser adapted  
to dispense the first mixture into a leads distal tip.

30 18. The apparatus of claim 17 further comprising a curing jig  
adapted to hold leads in place during the dispensing of the first mixture  
into a distal tip thereof.

19. The apparatus of claim 18 further comprising a heater adapted to heat at least a leads distal tip into which the first mixture has been dispensed to thereby cure said first mixture in the distal tip.

5           20. The apparatus of claim 19 wherein the dispenser is adapted to dispense uncured first mixture into a curing jig plate, the curing jig plate having at least one groove for receiving the first mixture, whereupon subsequent to curing of the first mixture in a groove, the cured mixture is formable into plugs adapted for insertion into a leads distal tip.

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21. An apparatus for forming a monolithic controlled release device (MCRD) mixture for use in a drug-eluting endocardial lead having a distal tip to facilitate the controlled release of the drug from the distal tip into cardiac tissue, the apparatus comprising:

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          mixing means for forming a mixture of an inflammation-reducing drug and a drug carrying silicone elastomer; and means for applying the mixture into a leads distal tip.

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22. The apparatus of claim 21 further comprising means for mixing the inflammation-reducing drug with a wetting fluid.

23. The apparatus of claim 21 further comprising means for curing the mixture applied to a leads distal tip.

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24. The apparatus of claim 23 wherein the curing means comprises means for heating the mixture in place at a predetermined temperature.

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25. The apparatus of claim 21 further comprising means for holding a lead in place for receiving the applied mixture.

26. The apparatus of claim 21 comprising means for mixing a base component and a curing component to thereby form the silicone elastomer.

5           27. An apparatus for forming a plug for use in a drug-eluting endocardial lead to facilitate the controlled release of a drug to cardiac tissue in a patient's heart, the apparatus comprising:

                    first mixing means for forming a mixture of a drug for  
                    reducing inflammation of cardiac tissue in the patient's heart  
10               following implantation of the lead and a silicone elastomer for  
                    carrying the drug, wherein the silicone elastomer comprises a base  
                    component and a curing component; and  
                    means for dispensing the mixture into a portion of the  
                    endocardial lead.

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28. The apparatus of claim 27 additionally comprising means for heating at least the portion of the lead containing the dispensed mixture to decrease the curing time.

20           29. The apparatus of claim 28 wherein the heating means heats the dispensed mixture to a temperature of at least 55° C.

30. The apparatus of claim 27 wherein the curing component is a platinum catalyst.

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31. The apparatus of claim 27 wherein the base component of the silicone elastomer comprises a mixture of a dimethylsiloxane polymer and a reinforcing silicone.

30           32. The apparatus of claim 27 wherein the drug comprises a steroid.

33. The apparatus of claim 32 wherein the steroid is dexamethansone sodium phosphate.

5 34. The apparatus of claim 27 additionally comprising a second mixing means for combining a silicone fluid with the drug to form the drug component as a fluid drug mixture to facilitate mixing with the base and curing components by the first mixing means.